

YOUNG CONAWAY STARGATT & TAYLOR, LLP

MELANIE K. SHARP
DIRECT DIAL: (302) 571-6681
DIRECT FAX: (302) 576-3333
msharp@ycst.com

THE BRANDYWINE BUILDING
1000 WEST STREET, 17TH FLOOR
WILMINGTON, DELAWARE 19801

P.O. BOX 391
WILMINGTON, DELAWARE 19899-0391

(302) 571-6600
(302) 571-1253 FAX
(800) 253-2234 (DE ONLY)
www.youngconaway.com

May 13, 2008

BY E-FILE

The Honorable Mary Pat Thyng
United States District Court of Delaware
844 North King Street
Wilmington, DE 19801

Re: *Human Genome Sciences, Inc. v. Amgen, Inc. et al.*
C. A. No.: 07-526-SLR-MPT
Reply to HGS' Letter Regarding Issue of Priority for § 146 Appeal

Dear Judge Thyng:

Defendants Amgen and Immunex ("Immunex") respectfully request an opportunity to address the misstatements of fact and law in HGS' May 5, 2008 letter (D.I. 36) regarding Immunex's request for clarification on the issue of priority on appeal (D.I. 35).

Immunex has always recognized that the scope of a 35 U.S.C. § 146 action includes both issues raised by the parties and issues decided by the Board. Immunex Letter Brief Regarding Issues on Appeal (D.I. 22), Section II(B), pp. 3-4; Memorandum Order (D.I. 33) 19:13-14 ("HGS is correct that this court's § 146 review is not limited to issues decided by the Board and Immunex acknowledges that in its submission."). However, Immunex has argued from the outset that the Court should not consider priority because priority involves many issues that were not raised or fully developed before the Board. D.I. 22, Section II(D)(1), pp. 5-6 ("None of these issues [conception, diligence, reduction to practice] were fully developed let alone decided by the Board in the interference."). As this Court recently recognized, failure to adequately develop the record at the Board level "leaves too much room for mischief in a § 146 appeal." Memorandum Opinion in related District of Delaware case, Civ. No. 07-780, dated May 9, 2008 ("May 9 Order"), 15:8-9.

Further, as the Court noted, HGS represented that the priority issues on appeal were the issues raised in its priority motion. D.I. 33, 20:14-15 ("HGS is seeking review on priority *based on legal theories set forth in its Motion 7.*") Now, in light of Immunex's request for clarification, it is clear that HGS intends to conduct discovery on priority issues that were never raised before the Board. If the ruling that "the court will consider the priority issue" from the Memorandum Order (D.I. 33, 21:3-4) is meant to include review of Immunex's priority case, this would be a clear error of law premised upon a clear error of fact because HGS' filing of its priority brief does not raise Immunex's priority case.

As noted in the Memorandum Order, to qualify for consideration under § 146, a party must raise an issue in the manner specified in the PTO's interference regulations, or undeniably place the issue before the Board and insist that the issue be resolved. D.I. 33 at 17-18. In the

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interference below, the Board terminated the proceedings *before* Immunex had an opportunity to present its priority case. The dates for Immunex's priority case are stated in Immunex's priority statement, but that statement does not "raise" Immunex's priority case for consideration in a 146 action. "A significant body of case law leads to the conclusion that including a factual assertion within a preliminary statement before the Board is not 'raising an issue' within the meaning of §146." Abbott Labs v. City of Hope, 224 F. Supp. 2d 1200, 1202 (N.D. Ill. 2002) (citing General Instrument, 995 F.2d at 214; Conservolite, 21 F.3d at 1102). HGS' response does not address the black letter law that Immunex's priority case cannot be on appeal.

This Court recognizes that "it is clear that the fundamental purpose of interference proceedings is to give the Board a full and fair opportunity to determine priority." May 9 Order, 15:2-3. Contra to this purpose, HGS requests that the Court consider Immunex's priority case using its discretion under Conservolite. Compelling circumstances must be present, however, in order for the Court to consider issues not raised before the Board in a § 146 action. Conservolite, 21 F.3d at 1102; Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 592 (Fed. Cir. 1997); Memorandum Order, D.I. 33 at 22. HGS does not even suggest a compelling reason to consider Immunex's priority case in this action. Without a compelling reason, consideration of Immunex's priority is an "effective usurpation of the Board's original jurisdiction to determine priority." May 9 Order, 15: 6-8.

HGS asserts, without support, that there is no such thing as half of a priority dispute. D.I. 36, p. 5. The only priority issues the Court considered in ruling that priority had been raised below were the issues raised by HGS Motion 7. As noted, the Court's discretion to consider issues not raised below is limited to compelling circumstances and none are present here. The decision to exclude issues in a § 146 action that the Board did not decide is left to the sound discretion of the Court and reviewable for abuse of discretion. General Instrument, 995 F.2d at 214. HGS requests that the parties' priority cases be decided together; Immunex agrees that such an action fosters judicial economy. However, the only appropriate forum at this juncture is the Board of Patent Appeals and Interferences on remand, if remand is necessary after reviewing the Board decision on substantive motions.

Immunex respectfully reiterates its request for clarification on this matter.

Respectfully,

/s/ *Melanie K. Sharp*

Melanie K. Sharp (No. 2501)

cc: Clerk of the Court (Hand Delivery)
 John G. Day, Esquire (via e-mail)
 Steven J. Balick, Esquire (via e-mail)
 Lauren E. Maguire, Esquire (via e-mail)